K033513
page 1 of 1

JAN 15 2004

9.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

   Philips Medical Systems

   This summary was prepared on November 5, 2003.

2. The name of this device is the EASI ECG. Classification names are as follows:

Classification	ProCode	Description
870.2350, II	74 DRW	Adapter, Lead Switching, electrocardiograph

3. The new device is substantially equivalent to the previously cleared EASI Algorithm cleared under K020456 and Philips patient monitors cleared under K990476 & K032858.

4. The modification is a change that provides additional derived leads, alternative electrode placements, and an expanded patient population.

5. EASI ECG is indicated for use by health care professionals whenever there is a need to monitor ECG of adult, pediatric, or neonatal patients including arrhythmia monitoring or ST segment changes of adult patients, to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

6. The new device has the same technological characteristics as the legally marketed predicate device.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved performance verification to a 1185 patient database and comparison of results to the predicate and direct ECG. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that EASI ECG meets all requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2004

Philips Medical Systems
c/o Mr. David Osborne
Quality Program Manager
Cardiac and Monitoring Systems
3000 Minuteman Road
Andover, MA 01810-1099

Re: K033513
Trade Name: EASI ECG
Regulation Number: 21 CFR 870.2350
Regulation Name: Electrocardiograph Lead Switching Adaptor
Regulatory Class: Class II (two)
Product Code: DRW
Dated: November 5, 2003
Received: November 6, 2003

Dear Mr. Osborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033513

Page _____ of _____

510(k) Number (if known): K033513

Device Name: EASI ECG

Intended Use: EASI ECG is intended for monitoring multiple leads of ECG of adults, pediatrics and neonates.

ST Segment monitoring is restricted to adult patients only.

Indications for Use: EASI ECG is indicated for use by health care professionals whenever there is a need to monitor ECG of adult, pediatric, or neonatal patients including arrhythmia monitoring or ST segment changes of adult patients, to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms, including:

- —Assessment of symptoms that may be related to rhythm disturbances of the heart
- —Patients with palpitations
- —The evaluation of arrhythmias in patients from neonatal to pediatric to adult age
- —Assessment of risk in patients with or without symptoms of arrhythmia
- —Assessment of efficacy of anti-arrhythmic therapy
- —Assessment of pacemaker function
- —Assessment of symptomatic or asymptomatic patients, to evaluate for, ischemic heart disease and arrhythmia analysis during exercise testing
- —Assessment of ST segment analysis in adult patients

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033513

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use**

(Per 21 CFR 801.109)

(Optional Format 1-2-96)